REMARKS

Status of Claims

Upon entry of this Amendment, claims 1-44 and claims 57-96 will be pending. Claims 45-56 have been cancelled without prejudice or disclaimer. Applicants reserve the right to prosecute the subject matter of the cancelled claims in a continuation, continuation-in-part or divisional application. Claims 57-96 have been added to recite additional embodiments of the invention. Support for the added claims can be found throughout the specification as filed, as described below. Applicants assert that no new matter has been added by way of these amendments.

Added claims 57-79 are directed to a dosage unit formulation comprising the recited antisense oligonucleotide. Support for added claims 57-79 can be found throughout the specification as originally filed. Specifically, support for a "dosage unit formulation" can be found, for example, at page 29, lines 8-11. Support for the oligonucleotide lengths recited in new claims 58-60 can be found throughout the specification as originally filed, for example, at page 10, lines 18-23. Support for added claims 61-62 can be found throughout the specification as filed, for example, at Examples 12 and 13. Support for the modified oligonucleotides recited in new claims 63-64 can be found in, for example, at page 12, line 5, and at page 11, line 15.

Support for added claims 65-70 can be found throughout the specification as filed. Support for a "solid tumour" which can be "drug-resistant" or "metastatic" can be found, for example, at page 37, lines 3-6. In particular, support for "a prostate tumour" can be found, for example, at page 32, lines 20-22; at page 37, line 3-11; at Table 1; at Table 2; and at the Examples. Support for "metastatic" can be found, for example, at page 36, line 7 and support for "hormone refractory" can be found, for example, at page 36, line 26 to page 37, line 2; and at Example 13.

Support for the dose ranges recited in new claims 71-72 can be found throughout the specification as filed. In particular, support for "between about 124.8 $mg/m^2/day$ and about 356.5 $mg/m^2/day$" can be found, for example, at page 38, lines 4 to 25; and at

Example 12. Support for "between about 124.8 mg/m^2/day and about 210.9 mg/m^2/day" can be found, for example, at page 38 lines 4 to 25; and at Example 13.

Support for the routes of administration recited in new claims 73-75 can be found throughout the specification as filed in. In particular, support for "parenteral administration" can be found, for example, at page 37, line 27 and support for "intravenous administration" can be found, for example, at page 38, lines 2 to 3. Support for an "injectable formulation" can be found, for example, at page 37, line 28-29; at page 38, lines 1-3; at Example 12, pages 67-68; and at Example 13, pages 77-78.

Support for administration of the dosage unit formulation in combination with one or more chemotherapeutic drugs as recited in new claims 76-79 can be found in, for example, at page 39 and lines 16 to 19. In particular, support for "docetaxel" can be found, for example, at pages 20 to 25; at Table 1; and at Example 13. Support for "between about 45 mg/m^2/day and about 75 mg/m^2/day" and "between about 60 mg/m^2/day and about 75 mg/m^2/day" can be found, for example, at page 41, lines 1 to 8; and at Example 13.

Added claims 80-96 are directed to a method treating a solid tumour in a human comprising administering to said human the claimed dosage unit formulation. Support for added claims 80-96 can be found throughout the specification as filed, for example at page 29, at pages 32-38, and as described above for new claims 57-79.

Applicants respectfully request entry of the amendments, reconsideration of the unity of invention determination, and allowance of the pending claims.

Related Applications

Applicants would like to bring to the attention of the examiner the following related applications: 08/904,901; 09/230,521; 09/249,247; 09/451,673; and 10/447,136.

Response to Restriction Requirement

The Restriction Requirement requires that Applicants elect one of the following allegedly distinct inventions:

> Group I, claim(s) 1-44, drawn to an antisense oligonucleotide derived from SEQ ID NO: 1.
>
> Group II, claim(s) 45-56, drawn to the use of an antisense oligonucleotide in the manufacture of a medicament.

Added claims 57-79 are directed to a formulation of an antisense oligonucleotide derived from SEQ ID NO: 1 and added claims 80-96 are directed to a method of use thereof. Accordingly, Applicants respectfully submit that added claims 57-79 belong to Group I and added claims 80-96 create a new Group III. Applicants therefore propose that the restriction requirement be rewritten as follows:

> Group I, claim(s) 1-44 and 57-79, drawn to an antisense oligonucleotide derived from SEQ ID NO: 1.
>
> Group II, claim(s) 45-56, drawn to the use of an antisense oligonucleotide in the manufacture of a medicament.
>
> Group III, claim(s) 80-96, drawn to a method of treating a solid tumor in a human with the formulation of Group I.

Traversal

Applicants respectfully submit that the claims relate to a single general inventive concept, and therefore do not lack unity of invention. According to M.P.E.P. § 1850, when the Office considers international applications during the national stage as a Designated or Elected Office under 35 U.S.C. § 371, PCT Rule 13.1 and 13.2 will be followed when considering unity of invention of claims of different categories without regard to the practice in national applications filed under 35 U.S.C. § 111. In applying PCT Rule 13.2 to national stage applications under 35 U.S.C. 371, examiners should consider for unity of invention all the claims to different categories of invention in the

application and permit retention in the same application for searching and/or preliminary examination, claims to the categories which meet the requirements of PCT Rule 13.2.

The proper test in determining unity of invention is whether the group of inventions are considered linked so as to form a single general inventive concept. Here, the Examiner alleges that Wright, et al. (US Pat. 6,121,000) destroys unity of invention because "the special technical feature, antisense oligonucleotides directed to Ribonucleotide Reductase R1, does not make a contribution over the prior art as evidenced by Wright, et al." See Office Action at page 2. Applicants respectfully submit that the claims are drawn to antisense oligonucleotides having, *inter alia*, at least 7 consecutive nucleotides from SEQ ID NO: 1, and uses thereof. Such antisense oligonucleotides are not described in Wright *et al.*, and as such, this reference can not destroy unity of invention.

In view of the above, Applicants respectully submit that the Office Action does not set forth reasons as to why the claims are not so linked by a special technical feature as to form a single inventive concept. Under unity of invention, applicant has a right to include in a single application those inventions which are so linked as to form a single general inventive concept. *See PCT Rule 13.2.* A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression "special technical feature" is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art. Applicants respectfully submit that the claims do share a special technical feature in that all of the claims are directed to varied aspects antisense oligonucleotides having, *inter alia*, at least 7 consecutive nucleotides from SEQ ID NO: 1.

Applicants respectfully request reconsideration of the unity of invention determination and allowance of the pending claims.

Election

Should the restriction of the pending claims be maintained, Applicants hereby provisionally elect Group I (1-44 and 57-79), **with traverse**. Regarding the election of species, Applicants provisionally elect "prostate tumour" and "docetaxel" with **traverse**.

Should the Examiner disagree with the Applicants proposed grouping of the claims, Applicants hereby provisionally elect claims 57-79, and provisionally elect "prostate tumour" and "docetaxel", with traverse.

Request for Rejoinder

Should the restriction of the pending claims be maintained, it is the Applicants' understanding that the claims of Group III, claims 45-56, shall be rejoined upon allowance of a linking claim. Where an Applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn method claims that depend from or otherwise include all the limitation of the allowable product claims will be rejoined in accordance with the provisions of MPEP 821.04. Method claims that depend from or otherwise include all limitation of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance. Accordingly, should the claims of Group I, drawn to the product, be allowed, Applicants respectfully request rejoinder of Group III, claims 45-56, which are method claims that include all the limitations of the recited product claims

CONCLUSION

An indication of allowance of all claims is respectfully solicited. Early notification of a favorable consideration is respectfully requested. In the event any issues remain, Applicant would appreciate the courtesy of a telephone call to their counsel to resolve such issues and place all claims in condition for allowance.

It is believed that no additional fees are required with this submission. However, in the event that additional fees are deemed necessary, or in the event of any variance between the amount enclosed and the fees determined by the USPTO, please charge or credit any such variance to the undersigned's Deposit Account No. 50-0311, Reference No. 21892-517.

Respectfully submitted,

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